

## **Flex Policy Implementation by Campus**

<b>EXPEDITED REVIEW CATEGORIES</b>		
<p>Expedited review procedures may be used when ALL the following criteria are true:</p> <ul style="list-style-type: none"> <li>• The research activities present no more than minimal risk to human subjects</li> <li>• Identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.</li> <li>• The research is not classified</li> </ul> <p>The research falls into one or more of the following categories:</p>		
	<b>HSIRB</b>	<b>UPIRB</b>
<p>1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <p style="padding-left: 20px;">(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)</p> <p style="padding-left: 20px;">(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.</p>	No flex	No flex
<p>2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <p style="padding-left: 20px;">(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</p> <p style="padding-left: 20px;">(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.</p>	No flex	No flex
<p>3. Prospective collection of biological specimens for research purposes by noninvasive means.</p> <p>Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;</p>	No flex	2yr approval

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<p>(c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.</p>		
<p>4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)</p> <p>Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.</p>	<p>Medical devices: no flex 2 yr approval for non-medical device studies</p>	<p>2yr approval</p>

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<p>5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. <a href="#">45 CFR 46.101(b)(4)</a>. This listing refers only to research that is not exempt.)</p>	<p>Specimens: no flex</p> <p>2yr approval for studies involving data <b>collection/abstraction</b> only whether retrospective or prospective (chart review)</p> <p>Once data collection is complete and data is to be maintained or analyzed in an identified or de-identified manner, studies can be reviewed under exempt 8</p>	<p>Specimens: no flex</p> <p>2yr approval for studies involving prospective data <b>collection</b></p> <p>Once data collection is complete and data is to be maintained or analyzed in an identified manner, studies can be reviewed under exempt 8</p>
<p>6. Collection of data from voice, video, digital, or image recordings made for research purposes.</p>	<p>2 yr approval</p>	<p>2yr approval</p>
<p>7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. <a href="#">45 CFR 46.101(b)(2)</a> and (b)(3). This listing refers only to research that is not exempt.)</p>	<p>2 yr approval</p>	<p>2yr approval</p>

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<b>EXEMPT CATEGORIES</b>	<b>HSIRB</b>	<b>UPIRB</b>
<p>7. Non-funded research, involving no greater than minimal risk, that does not conform to a specific exempt category under 45 CFR 46.</p> <p>Examples include:</p> <ul style="list-style-type: none"> <li>▪ Online surveys, in-person focus groups and surveys conducted in a group setting of minors aged 14-17 that do not collect sensitive information, no greater than minimal risk</li> <li>▪ Behavioral games</li> <li>▪ Studies of leadership traits of non-public, non-elected officials</li> <li>▪ Studies requiring performance of tasks that incur no risk</li> <li>▪ Studies involving focus groups, oral histories, ethnographies, studies utilizing eye-tracking technology (unfunded)</li> </ul>		
<p>8. Research, involving no greater than minimal risk, where activity is limited to study of existing (or prospective at IRB discretion) identifiable data.</p> <p>Examples include:</p> <ul style="list-style-type: none"> <li>- Medical record reviews where data was extracted from records</li> <li>- Data analysis of information already collected from court records</li> </ul> <p>Exempt 8 does not require continuing review; however, a HIPAA waiver may still be required. Studies that typically fall under expedited category 5 (involving analysis only of already collected data/documents/records) may now qualify for exempt category 8.</p> <p>All studies regardless of initial risk determination, that are now limited to data analysis and not federally funded, may qualify for exempt category 8.</p>		